

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* ALES PROKOP

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Appeal No. 2003-0681  
Application No. 09/169,459

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ON BRIEF

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Before WILLIAM F. SMITH, TIMM, and GRIMES, *Administrative Patent Judges*.  
TIMM, *Administrative Patent Judge*.

***DECISION ON APPEAL***

This appeal involves claims 1-3, 6-11, 13, 15, and 30 which are all the claims pending in the application.<sup>1</sup> We have jurisdiction over the appeal pursuant to 35 U.S.C. § 134.

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<sup>1</sup>Claims 12, 14, 16-25, and 27-29 were cancelled after the Final Rejection (After-Final Amendment filed December 19, 2001, Paper No. 17 was entered as per Advisory Action mailed January 18, 2002, Paper No. 18; see also Answer, p. 2).

### ***INTRODUCTION***

The claims are directed to a method of making nanoparticles comprised of a quaternary polyanionic/cationic complex. Appellants define a nanoparticle as a “submicroscopic (less than 1 micrometer in size) solid object, essentially of regular or semi-regular shape.” (specification, p. 16, ll. 19-21). The complex is formed by contacting at least two polyanionic polymers with at least two cations. Claim 1 is illustrative of the subject matter on appeal:

1. A method of making nanoparticles comprised of a polyanionic/cationic complex, wherein said nanoparticles do not dissolve in physiological media for at least one day so as to be useful in drug delivery, said method comprising the steps of:

contacting at least two polyanionic polymers with at least two cations, wherein said contacting is by a process selected from the group consisting of capturing a mist of droplets comprising said polyanionic polymers in a liquid comprising said cations; and, capturing a mist of droplets comprising said cations in a liquid comprising said polyanionic polymers.

All of the pending claims stand rejected under 35 U.S.C. § 103(a). As evidence of obviousness, the Examiner relies upon the following prior art references:

Andrianov et al. (Andrianov)	5,529,777	Jun. 25, 1996	
Krone et al. (Krone)	5,700,459		Dec. 23, 1997
Wang et al. (Wang)	5,997,900		Dec. 7, 1999
			( filed Apr. 16, 1997)

The specific rejection is as follows: Claims 1-3, 6-11, 13, 15, and 30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wang in view of Andrianov and Krone.

We reverse for the reasons that follow.

***OPINION***

The examiner bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). This burden must be satisfied by the examiner, otherwise, without more, applicants are entitled to a patent. *Id.*

To satisfy the burden, the examiner must establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the examiner must not only identify where in the references the limitations of the claim are taught, the examiner must also identify what in the prior art supports a finding of a reason, suggestion, or motivation to modify the prior art or to combine prior art references to arrive at the claimed invention. *See In re Huston*, 308 F.3d 1267, 1280, 64 USPQ2d 1801, 1810 (Fed. Cir. 2002); *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). “The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some case the nature of the problem to be solved.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). But, importantly, the evidence must support the rationale of the examiner. *Lee*, 277 F.3d at 1343, 61 USPQ2d at 1433.

The rejection is based on the conclusion that it would have been obvious to one of ordinary skill in the art at the time of invention to modify the size of Wang’s microparticles (Answer, p. 5). As found by the Examiner, Wang describes microencapsulation of antibodies using the required quaternary complex (Answer, p. 3). The Examiner acknowledges that Wang

does not describe forming nano-sized microparticles and turns to Krone for a teaching of nanoparticles using a polyelectrolyte complex containing an active agent (Answer, p. 4).

Because Krone describes how to form nanoparticles for delivery of the active substance in vivo, the Examiner concludes that one of ordinary skill in the art would have been motivated to modify the size of the microparticles of Wang to improve the delivery profile of a bioactive agent of choice (Answer, p. 5).

The problem is that Wang does not intend to use the encapsulated antibodies described therein as active agents, rather, Wang uses the encapsulated antibodies in tests to assess capsule permeability (Wang, col. 3, ll. 1-10 and Example 1). Through the permeability tests, Wang identifies capsule complexes that protect cells encapsulated therein from immune attack while allowing the influx of molecules important for cell function/survival and the efflux of desired cellular products (Wang, col. 1, ll. 31-37, col. 3, ll. 1-10). The capsules of Wang are to be stable for long periods of time to protect cells from immune attack (Wang, Example 14). Krone uses polyelectrolyte complexes different than Wang to prepare micro/nanoparticles which carry active agents. Release of the active agents occurs upon dissolution of polyelectrolyte complexes (Krone, col. 2, ll. 26-29). While Krone expresses an interest in forming nanoparticles, the polyelectrolyte system and properties required in the intended use are different. The fact finding in the rejection falls short of establishing a link between the polyelectrolyte complexes of Wang and a reason, suggestion, or motivation to form nanoparticles with those complexes.

We conclude that the Examiner has failed to establish a *prima facie* case of obviousness with regard to the subject matter of claims 1-3, 6-11, 13, 15, and 30.

***CONCLUSION***

To summarize, the decision of the Examiner to reject claims 1-3, 6-11, 13, 15, and 30 under 35 U.S.C. § 103(a) is reversed.

REVERSED

WILLIAM F. SMITH  
Administrative Patent Judge

CATHERINE TIMM  
Administrative Patent Judge

ERIC GRIMES  
Administrative Patent Judge

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BENJAMIN A. ADLER  
8011 CANDLE LANE  
HOUSTON, TX 77071